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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/071,521	02/08/2002	Lere Bao	PTZ-007	1273

959 7590 05/04/2005

LAHIVE & COCKFIELD, LLP.
28 STATE STREET
BOSTON, MA 02109

EXAMINER

DAVIS, MINH TAM B

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 05/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/071,521

Applicant(s)

BAO ET AL.

Examiner

MINH-TAM DAVIS

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1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 January 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,5,7-16 and 25-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,5,9,11-16 and 24-35 is/are rejected.
- 7) ☒ Claim(s) 7, 8, 10 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The following are the remaining rejections.

NEW OBJECTION

Claims 7, 8, 10 are objected to under 37 C.F.R. § 1.75(c) as being in improper form, because they are multiple dependent claims and are dependent upon claims 5, 7, and 5, respectively, which are multiple dependent claims, and a multiple dependent claim cannot depend from any other multiple dependent claim. See M.P.E.P. § 608.01(n). Accordingly, the claims 7, 8, 10 have not been further treated on the merits.

It is noted that upon amendment claims 7, 8, 10 for proper claim dependency, the pending objection and 112, first paragraph rejection would still be applied to the amended claims 7, 8, 10.

Accordingly, claims 1-2, 4-5, 9, 11-16, 24-35 are examined in the instant application.

OBJECTION

1. Claims 1, 5, 9, 15-16, 24-35 remain objected to because it is not clear in claim 1 how to facilitate the diagnosis of prostate cancer by evaluating a test done to facilitate the diagnosis of prostate cancer (TDPCA).

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Applicant argues that the specification on page 8, lines 17-26 defines the term TDPCA, and that claim 1 has been amended to indicate the meaning of the term "TDPCA".

It is noted that the specification on page 8, lines 17-26 does not even refer to the term TDPCA. It is further noted that p.11, lines 21 in the specification discloses that "TDPCA" is a test done to facilitate the diagnosis of prostate cancer. The specification further discloses in the paragraph on p.11 following line 21 examples of different markers and different tests, such as PSA test, etc...

Objection remains, because it is not clear in claim 1, which type of test, which is done to facilitate the diagnosis of prostate cancer, is referred to.

Further, it is still not clear in claim 1 how to facilitate the diagnosis of prostate cancer by evaluating a test done to facilitate the diagnosis of prostate cancer (TDPCA), nor is it clear what kind of evaluation is referred to.

2. Claims 2, 5, 9, 15-16, 24-35 remain objected to for the use of the abbreviated language TDPCA in claim 2. Further, it is not clear which TDPCA is referred to.

3. Claim 33 remains objected to for the use of the language "a percent-free prostate specific antigen of between about 15 and about 25%", for reasons already of record in paper of 07/16/04.

Applicant argues that the term is intended to mean the percent of free, i.e. unbound, PSA out of the total amount of PSA. Applicant argues that the specification teaches on page 13, lines 25-34 and in table 2 on page 14 examples of bound PSA.

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It is noted that the specification does not teach on page 13, lines 25-34 examples of bound PSA. It is further noted that table 2 is on page 28, and not on page 14.

The specification discloses on page 27, last paragraph, that PSA exists in 2 forms in the blood: protein bound and free, and that in BHP, there is generally a higher percentage of free (as opposed to bound) PSA than in prostate cancer.

Claim 33 remains objected to, because it is not clear what "a percent-free prostate specific antigen of between about 15 and about 25%" is.

This objection could be obviated by amending claim 33, for example, to recite "a percent of free prostate specific antigen, as opposed to bound prostate specific antigen, of between about 15% and about 25%".

REJECTION UNDER 35 USC 112 FIRST PARAGRAPH, ENABLEMENT

Claims 1-2, 4-5, 9, 11-16, 24-35 remain rejected under 112 first paragraph for lack of enablement for a method for facilitating the diagnosis of prostate cancer in a subject, or a method for identifying metastatic prostate cancer, comprising assessing the level of "human Pin1 polypeptide" for reasons already of record in paper of 07/16/04.

Applicant amends the specification by reciting that human Pin1 has the amino acid sequence of SEQ ID NO:1.

Applicant argues that the human Pin1 is a polypeptide with a defined sequence, i.e. the sequence incorporated at p.9 of the specification.

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Applicant's arguments have been considered but are found not to be persuasive for the following reasons:

It is noted that the language "human Pin1" in claims 1-2, 4-5, 7-16, 24-35, without being specified that the human Pin1 is SEQ ID NO:1 in the claims, encompasses variants of SEQ ID NO:1, with unknown structure, in view that it appears from the definition on page 7, last paragraph, in the specification that Pin1 is a highly conserved class of protein, that catalyzes the isomerization of only phosphorylated Ser/Thr-Pro bonds, and that the definition of Pin1 in the amended paragraph to page 9 in the specification is not limiting.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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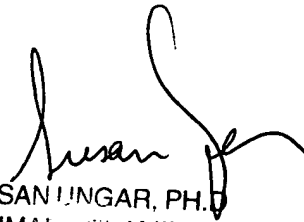
Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 571-272-0830. The examiner can normally be reached on 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JEFFREY SIEW can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MINH TAM DAVIS

May 02, 2005



SUSAN UNGAR, PH.D.
PRIMARY EXAMINER